

GLENN et al. - Appln. No. 09/257,188

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REMARKS

Reconsideration and allowance are respectfully requested.

The Examiner's courtesy in granting the interview of November 5, 2002 is gratefully acknowledged. Having supplied the missing references, Applicants request consideration of the Information Disclosure Statement and return of an initialed copy of Form PTO-1449 listing those documents.

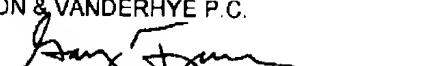
Claims 1-25, 27-51 and 60-95 are pending. The subject matter of pending claims 23-25, 27-30 and 87-91 is supported by the original description of the invention (e.g., page 8, lines 11-15, and page 23, lines 20-22, of the specification) and original claims 23-30. Example 12 (pages 60-62 of the specification) describes priming with an intramuscular injection into the hind thigh and then boosting by transcutaneous immunization on the back. Example 13 (pages 63-64 of the specification) describes adjuvant applied to the left ear and antigen applied to either the left or right ear (i.e., the same or different sites). Claim amendments are supported, inter alia, by page 6, lines 5-9, and page 26, lines 19-20, of the specification; new claims 92-95 are supported by Example 13 which describes the separate administration of antigen or adjuvant at the same site or different sites. Therefore, no new matter is added by these amendments. But if the Examiner should disagree, he is respectfully requested to point out the challenged limitation with particularity in the next Action so support may be cited in response.

Having responded to the objections and rejections in the Office Action (Paper No. 22), Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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APPENDIX
MARKED-UP VERSION TO SHOW CHANGES

IN THE CLAIMS

The claims are amended as follows.

1. (2x Amended) A method for inducing an antigen-specific immune response in a subject comprising:
 - a. pretreating an area of skin of said subject, whereby said pretreating disrupts at least the skin's stratum corneum but does not penetrate the skin's dermis; and
 - b. applying a formulation to said pretreated area, wherein said formulation comprises:
 - 1) at least one antigen sufficient to induce an antigen-specific immune response against a pathogen,
 - 2) at least one adjuvant present in an amount effective to induce said immune response to said at least one antigen, and
 - 3) a pharmaceutically acceptable carrier, wherein said pretreating enhances skin penetration by said formulation and thereby induces said immune response.

23. (2x Amended) A method for potentiating [inducing] an antigen-specific immune response in a subject comprising:
 - a. pretreating an area of skin of said subject, whereby said pretreating disrupts at least the skin's stratum corneum but does not penetrate the skin's dermis;
 - b. applying an adjuvant formulation to said pretreated area, wherein said adjuvant formulation comprises:
 - 1) at least one adjuvant present in an amount effective to promote said immune response and
 - 2) a pharmaceutically acceptable carrier, wherein said pretreating enhances skin penetration by said adjuvant formulation; and
 - c. administering to said subject a separate antigen formulation comprising at least one antigen sufficient to induce an antigen-specific immune response against a pathogen;

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such that said at least one antigen is processed by an antigen presenting cell and then presented to a lymphocyte to induce said immune response, and said at least one adjuvant potentiates said immune response.

28. (2x Amended) A method for potentiating [inducing] an antigen-specific immune response in a subject comprising:

- a. pretreating an area of the skin of said subject, whereby said pretreating disrupts at least the skin's stratum corneum but does not penetrate the skin's dermis;
- b. applying an antigen formulation to said pretreated area, wherein said antigen formulation comprises:

- 1) at least one antigen sufficient to induce an antigen-specific immune response against a pathogen and

- 2) a pharmaceutically acceptable carrier, wherein said pretreating enhances skin penetration by said antigen formulation; and

- c. administering to said subject a separate adjuvant formulation comprising at least one adjuvant in an amount effective to promote said immune response;

such that said at least one antigen is processed by an antigen presenting cell and then presented to a lymphocyte to induce said immune response, and said at least one adjuvant potentiates said immune response.

New claims 92-95 are added.